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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,542	12/11/2002	Johan Auwerx	234/231	6461

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,542	AUWERX ET AL.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 12-19* is/are rejected.

7)☒ Claim(s) *9-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to a response to a restriction requirement filed 12/17/04. Claims 20-25 have been cancelled. Claims 1-19 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-19) in the amendment filed 12/17/04 is acknowledged.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, pages 38, line 10, page 46, line 27, page 48, line 24, 25 and 26, page 52, line 25, 26 and 27 have sequences that are not accompanied by SEQ ID NO:s. If the sequences can be found in the sequence listing it would be remedial to insert the appropriate SEQ ID NO:s. If not, a new sequence listing, CRF and letter stating that the contents of the sequence listing and the CRF are the same and contain no new matter are required.

Claim Objections

Claim 1 and 5 are objected to because of the following informalities: In claim 1, PPARγ is abbreviated . PPARγ should be spelled out for clarity in its first occurrence in the claims.

In claim 5, the word "clones" is grammatically incorrect. It appears that applicants intended to state "cloned". Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7, 8, 12-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-4, 7, 8 and 15-19 recite a genus of control regions from a human PPARγ gene.

Claims 12-14 recite a genus of terminal deletion mutants of -125 to +196 of PPARγ1, -502 to +182 of PPARγ2 and –777 to +74 of PPARγ3 that are sufficient to initiate transcription.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical

and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The instant invention is drawn to control regions from peroxisome proliferator activated receptors (PPARγ) gene. The PPARγ gene has none exons and extends over more than 100 kilobases. By control regions, applicants refer to any element associated with assisting or impeding, initiation, termination or otherwise regulating the transcription of the gene such as promoters, enhancers, silencers and other regulatory elements such as regulators of pausing or anti termination. The control region can be upstream, downstream or in introns or exons and involved in regulating translation such as splicing (page 5, paragraph 1-18). Applicants only exemplify the control regions from PPARγ1, PPARγ2 and PPARγ3 genes that are found at the 5' end of the genes. These sequences were isolated and cloned, and presented respectively SEQ ID NO:s 1, 3 and 34 (see e.g. table III and page 7, line 2-page 8, line 27). Applicants teach that a variety of fragments obtained from these regions are preferred. Specifically, -125 to +196 and –3kb to +110 of the PPARγ1 gene, -502 to +182 and –1kb to +122 of the PPARγ2 gene and –777 to +74 and –800 to +1 of the PPARγ3 gene. Therefore, the disclosure has taught the isolation and characterization of the promoter region from PPARγ1, PPARγ2 and PPARγ3 that comprise all of the transcriptional elements within these sequences. Applicants' recitation of the broad class of control regions is not supported by written disclosure in the specification. The specification fails to convey the relevant identifying characteristics of the recited control regions nor provide a description of the control regions such that the structural requirements of the sequences can be envisioned other than for the three promoters. Neither applicant nor the prior

art provide a correlation between the human PPARγ gene sequences and the diverse collection of recited control regions. Given the large size and diversity of the recited control regions, the absence of disclosed or art recognized correlations between the human PPARγ gene sequences and the diverse collection of recited control regions and large number of potential control regions, it must be considered that any control region must be empirically determined. By disclosing the promoter control regions of PPARγ1, PPARγ and PPARγ3, the applicants have not reduced to practice the claimed invention. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

The specification teaches that the specific control regions identified above can be modified by terminal deletions without abolishing their regulatory functions (see page 11, line 13-17). However, applicants do not teach any deletions of the recited sequences or what domains or regions are required for the ability to function as control regions. Applicants teach that there is not a TATA box in PPARγ1,; that in PPARγ2 there is a TATA like element at –68 and a CAAT like consensus sequence at –56 and an AP-1 site at +10; in the PPARγ3 promoter several consensus sequence elements were identified, a TATA element at –34, a CAAT like consensus sequence at –118 and a potential E-box at –342. However, it is unclear if these elements are alone responsible for regulating the complex expression of PPARγ genes. Therefore, there is no disclosure of a structure-function relationship between the sequence of SEQ ID NO 1, 3 or 34 and transcriptional regulatory activity. Given the large size and diversity of fragments generated by deletion at the N and/or C-terminus and the inability to determine which will also have the essential element, it is concluded that the invention must be empirically

determined. In an unpredictable art, the disclosure of no species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Since the specific plasmids deposited at ATCC as accession number 97906 and 97862 are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. The invention does not recite use of any control region clone but instead specifically claims plasmids deposited at ATCC with deposit accession number 97906 and 97862. The plasmids deposited at ATCC under accession number 97906 and 97862 are commercially available, however, commercial availability is not necessarily evidence that the public will have access to the material for the live of a patent (see MPEP 2404.01). Others apparently deposited the plasmids of the invention, their availability in an unrestricted form for the life of a patent issued on the instant application cannot be ensured. Applicants must therefore deposit the specific plasmids recited in the claims and thus satisfy the deposit requirement under 37 CFR 1.801-1.809.

Conclusion

Claims 1-8 and 12-19 are rejected.

Claims 9-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

February 18, 2005

GERRY LEFFERS
PRIMARY EXAMINER